REMARKS

Status of the Claims

Claims 26, 30 and 31 are pending in the application. Claims 26, 30 and 31 are rejected.

Claims 26 and 31 are amended herein. No new matter is added to the amended claims.

Claim amendments

Claims 26 and 31 are amended to overcome the rejection under 35 U.S.C. §112, first paragraph. The language of claim 26 is amended such that the method recited in amended claim 26 is directed to specific peptide sequences. Thus, amended claim 26 is drawn to a method of producing activated T cells directed towards stratum corneum chymotrytic enzyme (SCCE). Such a method comprises the step of exposing dendritic cells to a human SCCE peptide selected from the group consisting of SEQ ID NOs: 31, 32, 33, 34, 35, 36, 80, 86, 99 or the human stratum corneum chymotrytic enzyme protein encoded by the DNA of SEQ ID NO: 30, thereby producing activated dendritic cells. The activated dendritic cells are then exposed to T cells, where the activated dendritic cells would present the stratum corneum chymotrytic enzyme peptide to the T cells, thereby producing activated T cells directed toward the stratum corneum chymotrytic enzyme.

Amended claim 31 does not use the term "at risk" and limits the source of the dendritic cells to individuals with ovarian cancer, prostate cancer, breast cancer or colon cancer. The inclusion of these cancers in claim 31 is supported by the results described in the Rule 132 Declaration of the inventor Dr. Timoth O'Brien provided herewith.

The 35 U.S.C. §112, First Paragraph Rejection

Claims 30-31 remain rejected under 35 U.S.C. §112, first paragraph for lack of enablement. Applicant respectfully traverses this rejection.

The Examiner had objected to the use of the term "suspected or at risk of getting cancer. Since the amended claim 31 still recited "at risk for ovarian cancer or prostate cancer", the Examiner has maintained the rejection of the claim.

Claim 31 is amended such that the amended claim no longer recites "at risk for ovarian or prostate cancer". Instead, the amended claim 31 is drawn to an individual with ovarian cancer, prostate cancer, breast cancer or colon cancer. The Declaration submitted herewith provides evidence that demonstrates amplification of stratum corneum chymotrytic enzyme in ovarian, breast and colon cancers by PCR. Based on the above-mentioned amendments and remarks, Applicant respectfully requests the withdrawal of rejection of claims 30-31 under 35 U.S.C. §112, first paragraph.

Claims 26 and 30-31 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement. Applicant respectfully traverses this rejection.

In general, the rejection was maintained since undue experimentation will be required to practice the claimed methods with a reasonable expectation of success due to lack of unpredictability in the art and the lack of established clinical protocols for effective dendritic cell therapies. Specifically, the Examiner states that the Declaration submitted along with the response provided only in vitro evidence for stratum corneum chymotrytic enzyme peptides with SEQ ID NO: 32 and 33 and not for the peptides other than SEQ ID NO: 32 and 33 and those that do not contain amino acids 5-13 or 123-131 of SCCE. Furthermore, the Examiner cites references such as **Cranmer** *et al.*, **Soruri** *et al.*, **Riott** *et al.*, **Geysen** *et al.* and **Wang** to show unpredictability in the art of clinical application of dendritic cell immunotherapy and binding of peptide to MHC complex *in vivo*.

Claims 26 and 31 are amended as discussed *supra*. Due to the amendment, claim 26 does not encompass any other peptide sequences other than those listed in the claim. Furthermore, claim 31 is amended to include cancers where the stratum corneum chymotrytic enzyme is amplified as described in the Declaration. The specification of the instant invention discloses the 9-mer peptides. The peptide encoded by the stratum corneum chymotrytic enzyme cDNA is known in the art. Additionally, the Declarations submitted along with the previous responses (mailed February 10, 2003 and January 20, 2006) provided evidence of immunogenicity of peptides with SEQ ID Nos. 32 and 33 by

demonstrating induction of cytotoxic T cell response. Thus, the instant specification provides ample evidence for the claimed method.

It is well known that "the specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without undue experimentation. Lack of working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. But because an enabling disclosure is required, Applicant need not describe all actual embodiments" (M.P.E.P. 2164.02). Although the Examiner has cited teachings of **Cranmer** *et al.* and **Soruri** *et al.* in an attempt to illustrate an unpredictability in the art of dendritic cell immunotherapy, Applicant submits that these teachings have not discouraged researchers from using dendritic cells, more specifically autologous dendritic cells in immunotherapy. In addition to the above-discussed fact, some of the references included with this response (*J Immunother*, 2001, 24(3): 242-249; *Int J Cancer*, 2001, 91(6): 749-756; *Clin Cancer Res*, 2001, 7(3 Suppl): 804s-810s; *Int J Cancer*, 2001, 93(6): 855-861; *Cytotherapy*, 2001, 3(1): 19-29; *Clin Cancer Res*, 2001, 7: 2277-2284; *Surg Today*, 2006, 36(6): 559-562; *Leuk Lymphoma*, 2006, 47(4): 675-682; *J Immunol*, 2006, 176(10): 6065-6075; *Blood*, 2006, 107(5): 1818-1827) that were published before the publication of the references cited by the Examiner also indicate that instant specification was enabling as of the filing date of the instant application. Thus, the art of dendritic cell immunotherapy was and is not unpredictable as stated by the Examiner.

As stated in *In* re Woody, 331 F.2d 636, 639, 141 USPQ 518, 520 (CCPA 1964): "It appears that no one on earth is certain as of the present whether the process claimed will operate in the manner claimed. Yet absolute certainty is not required by the law. The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." The novelty in the claimed invention relates in part to the identification of immunogenic stratum corneum chymotrytic enzyme peptides and not to the art of loading the dendritic cells with these peptides. Nevertheless, the induction of cytotoxic T cell response by some of the claimed stratum corneum chymotrytic enzyme peptides is sufficient to demonstrate the success in loading of dendritic cells with these peptides, culturing the loaded dendritic cells and production of immune activated T cells. Therefore, a fair reading of the instant specification along with the information available in the art should enable one of skill in the art to make and use the claimed invention without undue experimentation. Thus, Applicant submits that the scope of the claimed invention is commensurate with the enablement provided. Based on the above-mentioned amendments and remarks, Applicant respectfully requests the withdrawal of rejection of claims 26 and 30-31 under 35 U.S.C. §112, first paragraph.

This is intended to be a complete response to the Final Office Action mailed April 04, 2006. A Declaration by the Inventor, references cited by the Applicant in the response, a Petition For Extension of Time, and Form PTO-2038 are enclosed with this response. Applicant submit that the pending claims are in

condition for allowance. If any issues remain outstanding, please telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

Date: 8/4/06

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